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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,070	05/31/2001	Servaas Visser	433.006	1432

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EXAMINER

GUPTA, ANISH

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/787,070	<b>Applicant(s)</b> VISSER ET AL.	
	<b>Examiner</b> Anish Gupta	<b>Art Unit</b> 1654	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 December 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,6 and 8-10 is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) 3-5 and 7 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1654

### DETAILED ACTION

1. The amendment filed, 12-15-03, is hereby acknowledged. Claims 1, 5, 10 and 11 were amended and claims 12-14 were cancelled. Claims 1-11 are pending in this application.

2. The indicated allowability of claims 1-2, 6, 8-10 are withdrawn in view of the newly discovered reference(s) to Amankwa et al.

Rejections based on the newly cited reference(s) follow.

3. All rejections made in the previous office action and not cited herein are hereby withdrawn.

### Maintained Rejections

#### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 11 remains rejected under 35 U.S.C. 102(b) as being anticipated by Kizawa et al. (Chemical abstract No 1996:675428).

The claims are drawn to peptides of the sequence VYQHQAAMKPWIQPKTKVIPYVRY and VYQHQAAMKPWIQPKTKVIPYVRYL.

Applicants argue that the reference does not disclose the claimed process by which the products have been obtained. It is asserted that the peptides produced according to the process of the present invention therefore differ from conventional peptides and are thus novel due to the fact

Art Unit: 1654

that peptides of claim 11 exhibit preferred biological activity achieved as a result of performing hydrolysis after chromatographic absorption.

Applicants argument have been considered but have not been found persuasive.

As Applicants well knows, for a product by process claim, "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." Applicants have not established that the prior art product is sufficiently different from the claimed product such that the prior cannot anticipate nor render obvious the product.

For this reason, the rejection is maintained.

### **New Grounds for Rejections**

5. Claims 1, 2, 6, 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Calvete et al.

The claims are drawn to a process of production of peptide from a biological fluid where the peptides are subjected to in-situ hydrolysis on the chromatographic medium.

The reference states that boar sperm subject to centrifugation to separate spermatozoa and seminal plasma (see page 207). The plasma was dialyzed and subject to affinity chromatography on a heparin-sepharose CL-6B column (see page 207). The column was equilibrated with a TRIS-HCL buffer and then subject to proteolysis using either porcine pancreatic chymotrypsin or elastase (see page 207). This teaching meets limitation b in claim 1. The reference states the column was washed (meeting limitation c in claim 1) and the bound peptides were recovered eluting with TBS containing 1 M NaCl and further separated by HPLC (see page 207). Degradation with

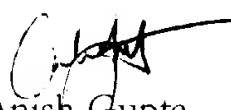
Art Unit: 1654

chymotrypsin yielded 11 fragments (see page 208). Thus, the reference disclosed on column digestion of peptides on an affinity chromatographic medium from a biological fluid. The reference, therefore, meets the claimed limitations.

6. Claims 3-5, 7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can normally be reached on (571) 272-0961. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
Anish Gupta  
Patent Examiner  
April 5, 2004